

immunoglobulin would have no effect on the breakdown of storage and sugars, protein and carbohydrates." (Official Action, paragraph bridging pages 5 and 6). In response, the claims have been amended to specify that the animal is given a fat-containing diet, thereby ensuring that the claimed immunoglobulin against lipase has a substrate in the feed. Accordingly, the claims are limited to a method enabled by the specification, i.e., a method for regulating the body weight of an animal that is fed a fat-containing diet. Therefore, the rejection can now be withdrawn.

Claims 1-9 stand rejected under 35 USC 112, 2nd paragraph as being vague and indefinite. The Examiner asserts that the preamble in claim 1 recites "A method for inhibiting body weight gained after eating" then argues "but the body of the claim does not set forth any limitation encompassing how inhibiting the amount of body weight gained is effected." (Official Action page 2, lines 14-17). However, the preamble to claim 1 recites something different, i.e., "A method for regulating the body weight of an animal." As presently amended, the claim is clear and definite because a person of skill in the art can readily determine if any given method is inside or outside the scope of the claims. If the animal is given a fat-containing diet that contains an amount of a liposome-encapsulated immunoglobulin against lipase which is effective to regulate body weight gain relative to the same diet without the immunoglobulin, the method is inside the claims.

The examiner asked "does applicant intend an effective amount of liposome-encapsulated immunoglobulin against lipase to bind lipase in the gut, thus inhibiting weight gain." (OA page 2, last paragraph). The claimed "effective amount" does not depend on intent but rather on the measurable *effect* of lipase, compared to its absence, on body weight with respect to a given diet.

In other enablement rejection, the Examiner has made similar arguments based on the mechanism of action. For example, page 4 of the Official Action states that one skilled in the art needs to know the mode of release, location of release and the viability of the encapsulated immunoglobulins against lipase after release from liposomes, apparently in order to determine the "affective amount." While such information might be needed to form a scientific theory about how the invention works, it is not needed

for enablement of how to regulate the body weight of an animal being given a fat-containing diet. The effective amount of liposome-encapsulated immunoglobulin can be determined by simple measurement of body-weight compared to a control sample consisting of the same diet but without the liposome-encapsulated immunoglobulin. The use of functional language, such as "effective amount" is generally accepted in U.S. patent practice.

CONCLUSION

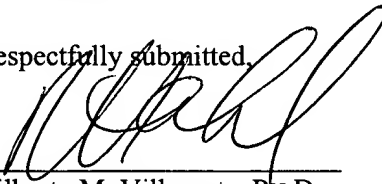
Applicant submits that the application is in condition for allowance. Favorable reconsideration, withdrawal of the rejections set forth in the above-noted Final Office Action, and an early Notice of Allowance are requested.

Applicant's undersigned attorney may be reached in our Washington, D.C. office by telephone at (202) 625-3680. All correspondence should be directed to our address given below.

AUTHORIZATION

Applicant believes there is no fee due in connection with this filing. However, to the extent required, the Commissioner is hereby authorized to charge any fees due in connection with this filing to Deposit Account 50-1710 or credit any overpayment to same.

Respectfully submitted,



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APPENDIX

MARKED-UP VERSION OF CLAIMS SHOWING CHANGES MADE

1. (Amended) A method for regulating the body weight ^{inhibiting} (of an animal) ^{gained after eating} comprising: feeding to an animal a fat-containing diet and an effective amount of a liposome-encapsulated immunoglobulin against lipase effective to inhibit body-weight gain.
2. (Amended) The method of claim [2] 1 wherein the immunoglobulin is an avian antibody.
6. (Amended) A mammalian food composition comprising fat and an effective amount of a liposome-encapsulated immunoglobulin [that binds to a] against lipase and effective to inhibit body-weight gain.